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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

MEINZER ET AL.

APPLICATION NO:

FILED:

FOR: OIL-FREE PHARMACEUTICAL COMPOSITIONS CONTAINING  
CYCLOSPORIN A

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants wish to call the Examiner's attention to the references cited on the attached forms PTO-1449 and PTO-892.

Some of the listed references are of record in parent Application No. 09/992,584 filed November 6, 2001, and copies are available therein.

Applicants wish to make of record the 14 references marked with an asterisk which are cited on attached forms PTO-1449 (sheets 1/9, 4/9, 5/9, 8/9, and 9/9) which are copied from grand-parent application 09/284,391 (now USP 6,475,519). Copies of these references are not enclosed since they are available to the Examiner in said grand-parent application.


Applicants wish to make of record Applications No. 09/690,400, October 17, 2000 (now USP 6,258,808); 09/668,677, September 22, 2000 (abandoned, now 09/738,104, December 15, 2000, pending); 09/637,260, August 11, 2000 (abandoned, now 10/427,861, May 1, 2003, pending); and 09/724,526, November 28, 2000 (now USP 6,503,526). A copy of each application was provided in said grand-parent application and is not enclosed.

Applicants also wish to make of record the reference newly cited on attached form PTO-1449, a copy of which is enclosed.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO forms.

Respectfully submitted,

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Gabriel Lopez  
Attorney for Applicants  
Reg. No. 28,440  
(862) 778-7882

encl: PTO-1449 (16 sheets) and PTO-892 (1 sheet) + 1 ref

Date: 2/18/04

**Notice of References Cited**Application/Control No.  
**09/992,584**Applicant(s)/Patent Under Reexam  
**MEINZER, ET AL**Examiner  
**JAMES M. SPEAR**Art Unit  
**1615**

Page 1 of 1

**U.S. PATENT DOCUMENTS**

|   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY <sup>1</sup> | Name           | Classification <sup>2</sup> |     |
|---|--|------------------------------|----------------|-----------------------------|-----|
| A | 6,475,519  | 11/2002                      | Meinzer, et al | 424                         | 456 |
| B |  |                              |                |                             |     |
| C |  |                              |                |                             |     |
| D |  |                              |                |                             |     |
| E |  |                              |                |                             |     |
| F |  |                              |                |                             |     |
| G |  |                              |                |                             |     |
| H |  |                              |                |                             |     |
| I |  |                              |                |                             |     |
| J |  |                              |                |                             |     |
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| L |  |                              |                |                             |     |
| M |  |                              |                |                             |     |

**FOREIGN PATENT DOCUMENTS**

|   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY <sup>1</sup> | Country | Name | Classification <sup>2</sup> |  |
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| N |  |                              |         |      |                             |  |
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| R |  |                              |         |      |                             |  |
| S |  |                              |         |      |                             |  |
| T |  |                              |         |      |                             |  |

**NON-PATENT DOCUMENTS**

|   | Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages |
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| U |  |
| V |  |
| W |  |
| X |  |

<sup>\*</sup> A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a).<sup>1</sup> Dates in MM-YYYY format are publication dates.<sup>2</sup> Classifications may be U.S. or foreign.

**INFORMATION DISCLOSURE CITATION**

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Group  
1615

**U.S. PATENT DOCUMENTS**

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|------|------|-------|----------|-------------|
|                     | AA |                 |      |      |       |          |             |
|                     | AB |                 |      |      |       |          |             |
|                     | AC |                 |      |      |       |          |             |
|                     | AD |                 |      |      |       |          |             |
|                     | AE |                 |      |      |       |          |             |
|                     | AF |                 |      |      |       |          |             |
|                     | AG |                 |      |      |       |          |             |
|                     | AH |                 |      |      |       |          |             |
|                     | AI |                 |      |      |       |          |             |
|                     | AJ |                 |      |      |       |          |             |
|                     | AK |                 |      |      |       |          |             |
|                     | AL |                 |      |      |       |          |             |

**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT NUMBER | DATE     | OFFICE | CLASS | SUBCLASS | TRANSLATION<br>YES NO    |                          |
|--|----|-----------------|----------|--------|-------|----------|--------------------------|--------------------------|
|  | AM | WO 94/25068     | 11/10/94 | PCT    |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AN | WO 95/22982     | 8/31/95  | PCT    |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AO | WO 95/32726     | 12/7/95  | PCT    |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AP | 2,230,440       | 10/24/90 | UK     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AQ |                 |          |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

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|--|----|--|
|  | AR |  |
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|  | AT |  |

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## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOC. NO.  
4-100-8388B/C1  
APPLICATION NO.APPLICANT  
MEINZER, ET AL.  
35 U.S.C. 371 FILING DATE

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME            | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|-----------------|-------|----------|-------------|
|                     | AA | 3,288,824       | 11/29/66 | Mahler et al.   | 260   | 410.6    |             |
|                     | AB | 3,813,345       | 5/28/74  | Urton           | 252   | 312      |             |
|                     | AC | 3,954,967       | 5/4/76   | Urton           | 424   | 81       |             |
|                     | AD | 4,073,943       | 2/14/78  | Wretlind et al. | 424   | 358      |             |
|                     | AE | 4,146,499       | 3/27/79  | Rosano          | 252   | 186      |             |
|                     | AF | 4,156,719       | 5/29/79  | Sezaki et al.   | 424   | 118      |             |
|                     | AG | 4,388,307       | 6/14/83  | Cavanak         | 424   | 177      |             |
|                     | AH | 4,567,161       | 1/28/86  | Posanski et al. | 514   | 23       |             |
|                     | AI | 4,571,926       | 2/25/86  | Scully          | 53    | 525      |             |
|                     | AI | 4,695,450       | 9/22/87  | Bauer et al.    | 424   | 22       |             |
|                     | AJ | 4,719,239       | 1/12/88  | Muller et al.   | 514   | 785      | 2/22/85     |
|                     | AK | 4,794,000       | 12/27/88 | Ecanow          | 424   | 457      | 1/8/87      |
|                     | AL | 4,797,272       | 1/10/89  | Linn et al.     | 424   | 59       |             |
|                     | AM | 6,258,808       | 7/10/01  | Hauer et al     | 514   | 227      |             |
|                     | AN | 4,803,081       | 2/7/89   | Falk et al.     | 424   | 488      |             |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE     | OFFICE                   | CLASS | SUBCLASS | TRANSLATION<br>YES NO               |                          |
|--|----|-----------------|----------|--------------------------|-------|----------|-------------------------------------|--------------------------|
|  | AM | 1,171,125       | 11/19/69 | United Kingdom           |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AN | 1,209,361       | 8/12/86  | Canada                   |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AO | 61/249,918      | 11/7/86  | Japan (see English Abst) |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AP | 135,171         | 3/27/85  | Europe                   |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AR | 2,222,770       | 3/21/90  | United Kingdom           |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|    |   |  |
|----|---|--|
| AR | Anonymous, Research Disclosure, No. 21143, and Res. Discl. No. 21143, "Galenic compositions comprising cyclosporin A [CS-A], (1981) |  |
|    | Beyer et al., Pharmazie in unserer Zeit, No. 2, "Micro-emulsions", pp. 55-60 (1983) - (Translation)                                 |  |
| AT |   |  |

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| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME             | CLASS | SUBCLASS | FILING<br>DATE |
|---------------------|----|-----------------|----------|------------------|-------|----------|----------------|
|                     | AA | 4,797,273       | 1/10/89  | Linn et al.      | 424   | 59       |                |
|                     | AB | 4,798,823       | 1/17/89  | Witzel           | 514   | 11       |                |
|                     | AC | 4,835,002       | 5/30/89  | Wolf et al.      | 426   | 590      |                |
|                     | AD | 4,888,239       | 12/19/89 | Brox             | 428   | 402.2    |                |
|                     | AE | 4,914,188       | 4/3/90   | Dumont et al.    | 530   | 317      |                |
|                     | AF | 4,963,367       | 10/16/90 | Ecanow           | 424   | 485      |                |
|                     | AG | 4,996,193       | 2/26/91  | Hewitt et al.    | 514   | 11       |                |
|                     | AH | 5,037,653       | 8/6/91   | Dawson           | 424   | 405      |                |
|                     | AI | 5,047,396       | 9/10/91  | Orban et al.     | 514   | 11       |                |
|                     | AJ | 5,154,754       | 10/13/92 | Damo et al.      | 71    | 79       |                |
|                     | AK | 5,342,625       | 8/1/94   | Hauer et al.     | 424   | 455      |                |
|                     | AL | 5,614,491       | 3/25/97  | Walch et al.     | 514   | 11       |                |
|                     | AM | 5,652,212       | 7/29/97  | Cavanak et al.   | 514   | 11       |                |
|                     | AN | 5,741,512       | 4/21/88  | Hauer et al.     | 424   | 450      |                |
|                     | AO | 5,759,997       | 6/2/98   | Cavanak          | 514   | 11       |                |
|                     | AP | 5,951,971       | 9/14/99  | Kawashima et al. | 424   | 78.04    |                |
|                     | AQ | 5,962,019       | 10/5/99  | Cho et al.       | 424   | 455      |                |
|                     | AR | 5,977,066       | 11/2/99  | Cavanak          | 514   | 11       |                |
|                     | AS | 5,985,321       | 11/16/99 | Brox et al.      | 424   | 451      |                |
|                     | AT | 6,007,840       | 12/28/99 | Hauer et al.     | 424   | 450      |                |
|                     | AU | 6,008,191       | 12/28/99 | Singh et al.     | 514   | 9        |                |
|                     | AV | 6,008,192       | 12/28/99 | Al-Razzak et al. | 514   | 11       |                |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE     | OFFICE         | CLASS | SUBCLASS | TRANSLATION              |                          |
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|  |    |                 |          |                |       |          | YES                      | NO                       |
|  | AW | 170,623         | 2/5/86   | Europe         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AX | 2,098,865       | 12/1/82  | United Kingdom |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AY | 2,206,119       | 12/29/88 | United Kingdom |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AZ | 2,209,671       | 5/24/89  | United Kingdom |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

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|--|----|-----------------|---------|--------------------------------|-------|----------|--------------------------|--------------------------|
|  |    |                 |         |                                |       |          | YES                      | NO                       |
|  | AA | 2,211,848       | 7/12/89 | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AN | 240789          | 5/1/46  | Switzerland (see English Abst) |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AO | 2,553,661       | 4/26/85 | France                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AP | 211,258         | 2/25/87 | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AQ | 256,856         | 2/24/88 | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|  |    |   |
|--|----|---|
|  | AB | Bhargava et al., Pharmaceutical Technology, pp.46,48,50,52,54, March 1987 |
|  | AC | Cavanak et al., Prog. Allergy, Vol. 38, pp.65-72 (1986)                   |
|  | AD | Ekman, Lipids, Vol. 22, No. 9, pp.657-663 (1987)                          |

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## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE     | OFFICE                         | CLASS | SUBCLASS | TRANSLATION                         |                          |
|--|----|-----------------|----------|--------------------------------|-------|----------|-------------------------------------|--------------------------|
|  |    |                 |          |                                |       |          | YES                                 | NO                       |
|  | AA | 274,431         | 7/13/83  | Europe                         |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AC | 3,315,805       | 11/8/84  | Germany (see English Abst)     |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AD | 314,689 B1      | 5/10/89  | Europe                         |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AE | 641,356         | 2/29/84  | Switzerland (see English Abst) |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AF | 86/02264        | 4/24/86  | PCT                            |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AF | 87/01035        | 2/26/87  | PCT                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AH | 2 015 339A      | 9/12/79  | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AI | 88/00059        | 1/14/88  | PCT                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | JJ | 895,724         | 7/28/83  | Belgium                        |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AK | 0 315 079       | 5/10/89  | Europe                         |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AL | 2 211 408       | 7/5/89   | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AM | 93/20833        | 10/28/93 | PCT                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AN | 378 893         | 7/25/90  | Europe                         |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AO | 91/08676        | 6/27/91  | PCT                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AP | 2 221 157       | 1/31/90  | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AQ | 2 228 198       | 8/22/90  | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AR | 2 224 205       | 5/2/90   | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AS | 2 218 334       | 11/15/89 | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AT | 361 928         | 4/4/90   | Europe                         |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AU | 2 230 440       | 10/24/90 | United Kingdom                 |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AV | 90/08537        | 8/9/90   | PCT                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AW |                 |          |                                |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |

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## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME             | CLASS | SUBCLASS | FILING<br>DATE |
|---------------------|----|-----------------|----------|------------------|-------|----------|----------------|
|                     | AA | 4,108,985       | 8/22/78  | Ruegger et al.   | 424   | 177      |                |
|                     | AB | 4,210,581       | 7/1/80   | Ruegger et al.   | 260   | 112.5    |                |
|                     | AC | 4,220,641       | 9/2/80   | Traber et al.    | 424   | 177      |                |
|                     | AD | 4,390,548       | 6/28/83  | Yamato et al.    | 424   | 321      |                |
|                     | AE | 4,482,576       | 11/13/84 | Boot et al.      | 426   | 603      |                |
|                     | AF | 4,652,406       | 3/24/87  | Lepper et al.    | 260   | 410.9    |                |
|                     | AG | 4,990,337       | 2/5/91   | Kurihara et al.  | 424   | 427      |                |
|                     | AH | 5,051,402       | 9/24/91  | Kurihara et al.  | 514   | 11       |                |
|                     | AI | 5,206,219       | 4/27/93  | Desai            | 514   | 3        |                |
|                     | AJ | 5,338,761       | 8/16/94  | Nakajima et al.  | 514   | 772      |                |
|                     | AK | 5,441,738       | 8/15/95  | Klein et al.     | 424   | 195.1    |                |
|                     | AL | 5,525,590       | 6/11/96  | Bollinger et al. | 514   | 11       |                |
|                     | AM | 5,639,724       | 6/17/97  | Cavanak          | 514   | 11       |                |
|                     | AN | 5,756,450       | 5/26/98  | Hahn et al.      | 514   | 9        |                |

## FOREIGN PATENT DOCUMENTS

|  |  | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRANSLATION |    |
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|  |  |                 |      |        |       |          | YES         | NO |
|  |  |                 |      |        |       |          |             |    |
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|  |  |                 |      |        |       |          |             |    |
|  |  |                 |      |        |       |          |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|  |    |   |
|--|----|---|
|  | AR | Ritschel et al., Pharmaceutical Research Vol. 5(10): Suppl. 108 PD 943 (1988)       |
|  | AS | Stupar et al., Goldschmidt Inforwist Essein., Vol. 52, pp. 22-28 (1982) translation |
|  | AT |   |

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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

|    |   |
|----|---|
| AA | Hahn, Biodegradable Tensides (1988)   |
| AB | Jayakrishnan et al., J. Soc. Cosmet. Chem. Vol. 34, pp.335-350 (1983)   |
| AD | Mubarak, Development and Testing of New Micro-emulsions (1982)  |
| AE | Muller et al., Pharm. Ind., Vol. 50 (11), pp. 1301-1306 (1988) (translation)  |
| AF | Muller et al., Pharm. Ind., Vol. 50(3), pp. 370-375 (1988) (translation)  |
| AG | Pohler, Micro-Emulsion Gels Structural Investigations and Galenical Properties (1983)   |
| AH | Remington's Pharmaceutical Sciences, 17th Edition, (A.R.Gennaro, , Ed.) Microemulsions, Chapter 20, pp. 298-299, Easton, Pennsylvania, (1985) |
| AI | Reymond et al., Pharmaceutical Research, Vol. 5(10), pp. 673-676 (1988)   |
| AJ | Reymond et al., Pharmaceutical Research, Vol. 5(10): 677-679 (1988)   |
| AK | Reymond, In Vitro In Vivo Model for the Absorption of Cyclosporin A (1986)  |
| AL | Ritschel et al., Meth. Find.Exp. Clin. Pharmacol., Vol. 11(4):281-287 (1989)  |
| AM | Ritschel et al., Meth.Find. Exp. Clin. Pharmacol., Vol. 12, pp.127-134 (1990)   |
| AN | Ritschel, Meth. Find. Exp. Clin. Pharmacol., Vol. 13(3), pp. 205-220 (1991)   |

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|    |  |
|----|--|
| AA | Takada et al., Int. J. of Pharmaceutics, Vol. 44, pp.107-116 (1988)                              |
| AB | Takada et al., Pharmaceutical Research, Vol. 3(1), pp.48-51 (1986)                               |
| AC | Takada et al., J. Pharmacobio-Dyn., Vol. 11, pp.80-87 (1988)                                     |
| AD | Takada et al., J. Pharmacobio-Dyn. Vol. 8, pp.320-323 (1985)                                     |
| AE | Takada et al., J. Pharmacobio-Dyn., Vol. 9, pp.156-160 (1986)                                    |
| AF | Tarr et al., Pharmaceutical Research, Vol. 6(1):40-43 (1989)                                     |
| AG | Yanagawa et al., J. Microencapsulation, Vol. 6(2), pp. 161-164 (1989)                            |
| AH | Ziegenmeyer et al., Acta Pharmaceutica Technologica, Vol. 26(4), pp.273-275 (1980) (translation) |
| AI | Ulman's Encyclopaedia of Industrial Pharmacy, Vol. A9, pp. 298-299 and 308-311 (1987)            |
| AJ | Carrigan et al., J. Pharm. Sci., Vol. 62, pp. 1476-1479 (1973)                                   |
| AK | Frazer et al., J. Physiol., Vol. 103, pp. 306-316 (1944)   |
| AL | Drewe et al., Br. J. Clin. Pharmac., Vol. 33, pp. 39-43 (1992)                                   |
| AM | Charley, Food Science, 2nd edition, pp. 224, 226, 228-229, John Wiley & Sons (1982).             |
| AN | The Merck Index, 9th Edition, (M. Windhold, Ed.)Merck & Co., Inc., Rahway, NJ, p. 1017 (1976)    |

**EXAMINER**

**DATE CONSIDERED**

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

**INFORMATION DISCLOSURE CITATION**

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ATTY. DOC. NO.  
4-100-8388B/C1  
APPLICATION NO.

APPLICANT  
MEINZER, ET AL.  
35 U.S.C. 371 FILING DATE

**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT NUMBER | DATE     | OFFICE                     | CLASS | SUBCLASS | TRANSLATION                         |                          |
|--|----|-----------------|----------|----------------------------|-------|----------|-------------------------------------|--------------------------|
|  |    |                 |          |                            |       |          | YES                                 | NO                       |
|  | AA | 616190          | 1/18/49  | United Kingdom             |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AB | 1 516 348       | 7/5/78   | Great Britain              |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AC | 97/34622        | 9/25/97  | PCT                        |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AD | 589 843         | 3/30/94  | Europe                     |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AE | 44 12 201       | 11/10/94 | Germany (see English Abst) |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AF | 195 39 860      | 5/9/96   | Germany (see English Abst) |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AG | 170 623         | 2/5/86   | Europe                     |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AH | 2120935         | 12/14/83 | United Kingdom             |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AI | 96/36316        | 11/21/96 | PCT                        |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AJ | 2098865         | 12/1/82  | United Kingdom             |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AK | 61/280435       | 12/11/86 | Japan (see English Abst)   |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AL | 4,003,844       | 8/16/90  | Germany (see English Abst) |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AM | 327,280         | 8/9/89   | Europe                     |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AN | 92/09299        | 6/11/92  | PCT                        |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AP | 298 351         | 2/20/92  | Germany (see English Abst) |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AQ |                 |          |                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AR |                 |          |                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AS |                 |          |                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AT |                 |          |                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AU |                 |          |                            |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |

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INFORMATION DISCLOSURE CITATION

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U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.  
4-100-8388B  
APPLICATION NO.  
09/992,584  
APPLICANT  
MEINZER ET AL.  
FILING DATE  
NOVEMBER 6, 2001

Sheet 1 of 1

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1615

U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME          | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|---------------|-------|----------|-------------|
|                     | AA | 5,589,455       | 12/31/96 | Woo           | 514   | 11       | 04/21/95    |
|                     | AB | 5,766,629       | 06/16/98 | Cho et al.    | 424   | 455      | 03/21/96    |
|                     | AC | 5,827,822       | 10/27/98 | Floc'h et al. | 514   | 11       | 03/25/96    |
|                     | AD | 5,834,017       | 11/10/98 | Cho et al.    | 424   | 455      | 08/25/95    |
|                     | AE |                 |          |               |       |          |             |
|                     | AF |                 |          |               |       |          |             |
|                     | AG |                 |          |               |       |          |             |
|                     | AH |                 |          |               |       |          |             |
|                     | AI |                 |          |               |       |          |             |
|                     | AJ |                 |          |               |       |          |             |
|                     | AK |                 |          |               |       |          |             |
|                     | AL |                 |          |               |       |          |             |

FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE     | OFFICE             | CLASS | SUBCLASS | TRANSLATION<br>YES NO               |                          |
|--|----|-----------------|----------|--------------------|-------|----------|-------------------------------------|--------------------------|
|  | AM | WO 95/11039     | 04/27/95 | WIPO (+ AU equiv.) |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AN | WO 97/00080     | 01/03/97 | WIPO (+ AU equiv.) |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AO | WO 98/40051     | 09/17/98 | WIPO               |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AP | WO 98/40094     | 09/17/98 | WIPO               |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AQ | 738 604         | 08/23/43 | DE                 |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|  |    |   |
|--|----|---|
|  | AR | Takada et al., "Development of a New Carrier for Cyclosporine A With Selectivity for Lymphatics", <i>Transplant. Proc.</i> , Vol. XIX, No. 1, pp. 1711-1712 (1987). |
|  | AS | Yasumura, Vol. 136, pp. 455-456 (1986) + translation.   |
|  | AT |   |

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## INFORMATION DISCLOSURE CITATION

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ATTY. DOCKET NO.  
4-100-8388A/PCT  
APPLICATION NO.  
09/284,391  
APPLICANT  
MEINZER, ET AL.  
35 U.S.C. 371 FILING DATE  
April 13, 1999

Group 1615

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME            | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|-----------------|-------|----------|-------------|
|                     | AA | 3,288,824       | 11/29/66 | Mahler et al.   | 260   | 410.6    |             |
|                     | AB | 3,813,345       | 5/28/74  | Urton           | 252   | 312      |             |
|                     | AC | 3,954,967       | 5/4/76   | Urton           | 424   | 78       |             |
|                     | AD | 4,073,943       | 2/14/78  | Wretlind et al. | 424   | 358      |             |
|                     | AE | 4,146,499       | 3/27/79  | Rosano          | 252   | 186      |             |
|                     | AF | 4,156,719       | 5/29/79  | Sezaki et al.   | 424   | 177      |             |
|                     | AG | 4,388,307       | 6/14/83  | Cavanak         | 424   | 177      |             |
|                     | AH | 4,567,161       | 1/28/86  | Posanski et al. | 424   | 199      |             |
|                     | AI | 4,571,926       | 2/25/86  | Scully          | 53    | 525      |             |
|                     | AI | 4,695,450       | 9/22/87  | Bauer et al.    | 424   | 168      |             |
|                     | AJ | 4,719,239       | 1/12/88  | Muller et al.   | 514   | 785      | 2/22/85     |
|                     | AK | 4,794,000       | 12/27/88 | Ecanow          | 424   | 457      | 1/8/87      |
|                     | AL | 4,797,272       | 1/10/89  | Linn et al.     | 424   | 59       |             |
|                     | AM | 4,803,081       | 2/7/89   | Falk, et al     | 424   | 488      |             |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE     | OFFICE                   | CLASS | SUBCLASS | TRANSLATION<br>YES NO               |                          |
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|  | AM | 1,171,125       | 11/19/69 | United Kingdom           |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AN | 1,209,361       | 8/12/86  | Canada                   |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AO | 61/249,918      | 11/7/86  | Japan (see English Abst) |       |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|  | AP | 135,171         | 3/27/85  | Europe                   |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |
|  | AQ | 2,222,770       | 3/21/90  | United Kingdom           |       |          | <input type="checkbox"/>            | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|   |    |  |
|---|----|--|
|   | AR | Anonymous, Chemical Abstracts, 1981:625610 (95:225610K) "Galenic compositions comprising cyclosporin A [CS-A]", (1981)   |
| * | AS | Anonymous, Derwent Abstracts, 1981-88539D, [48], "Galenic compsn. of cyclosporin-A for intravenous admin. - using reaction prod. of (hydrogenated) castor oil and ethylene oxide as carrier medium. Research Disclosure 0211043 (11/10/1981) |
|   | AT | Beyer et al., Pharmazie in unserer Zeit, Vol. 12(2): "Micro-emulsions", pp. 55-60 (1983) (English Equivalent) TBS  |

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|   |    | DOCUMENT NUMBER | DATE     | OFFICE                         | CLASS | SUBCLASS | TRANSLATION              |                          |
|---|----|-----------------|----------|--------------------------------|-------|----------|--------------------------|--------------------------|
|   |    |                 |          |                                |       |          | YES                      | NO                       |
|   | AA | 274,431         | 7/13/83  | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
| * | AB | 280,435         | 4/4/85   | Japan (see English Abst)       |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AC | 3,315,805       | 11/4/84  | Germany (see English Abst)     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AD | 314,689         | 5/10/89  | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AE | 641,356         | 2/29/84  | Switzerland (see English Abst) |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AF | 8,602,264       | 4/24/86  | PCT                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AF | 87/01035        | 2/26/87  | PCT                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AH | 2 015 339A      | 9/12/79  | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AI | 88/00059        | 1/14/88  | PCT                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | JJ | 895,724         | 7/28/83  | Belgium                        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AK | 0 315 079       | 5/10/89  | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AL | 2 211 408       | 7/5/89   | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AM | 93/20833        | 10/28/93 | PCT                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AN | 0 378 893       | 7/25/90  | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AO | 91/08676        | 6/27/91  | PCT                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AP | 2 221 157 A     | 1/31/90  | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AQ | 2 228 198 A     | 8/22/90  | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AR | 2 224 205A      | 5/2/90   | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AS | 2 218 334       | 11/15/89 | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AT | 0 361 928       | 4/4/90   | Europe                         |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AU | 2 230 440A      | 10/24/90 | United Kingdom                 |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AV | 90/08537        | 8/9/90   | PCT                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AW |                 |          |                                |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

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## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME             | CLASS | SUBCLASS | FILING<br>DATE |
|---------------------|----|-----------------|----------|------------------|-------|----------|----------------|
|                     | AA | 4,108,985       | 8/78     | Ruegger et al    | 514   | 11       |                |
|                     | AB | 4,210,581       | 7/80     | Ruegger et al.   | 530   | 321      |                |
|                     | AC | 4,220,641       | 9/80     | Traber et al.    | 514   | 11       |                |
|                     | AD | 4,390,548       | 6/1993   | Yamato et al     | 564   | 98       |                |
|                     | AE | 4,482,576       | 11/13/84 | Boot et al.      | 426   | 603      |                |
|                     | AF | 4,652,406       | 3/24/87  | Lepper et al.    | 260   | 410.9    |                |
|                     | AG | 4,990,337       | 2/5/91   | Kurihara et al.  | 424   | 427      |                |
|                     | AH | 5,051,402       | 9/24/91  | Kurihara et al.  | 514   | 11       |                |
|                     | AI | 5,206,219       | 4/27/93  | Desai            | 514   | 3        |                |
|                     | AJ | 5,338,761       | 8/16/94  | Nakajima et al.  | 514   | 772      |                |
|                     | AK | 5,441,738       | 8/15/95  | Klein et al.     | 424   | 195.1    |                |
|                     | AL | 5,525,590       | 6/11/96  | Bollinger et al. |       |          |                |
|                     | AM | 5,639,724       | 6/17/97  | Cavanak          | 514   | 11       |                |
|                     | AN | 5,756,450       | 5/26/98  | Hahn et al.      | 514   | 9        |                |

## FOREIGN PATENT DOCUMENTS

|  |  | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRANSLATION |    |
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|  |  |                 |      |        |       |          |             |    |
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|  |  |                 |      |        |       |          |             |    |
|  |  |                 |      |        |       |          |             |    |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|   |    |  |
|---|----|--|
|   | AR | Ritschel, et al., Pharmaceutical Research Vol. 5(10): Suppl. 108 PD 943 (1988) |
|   | AS | Stupar et al., Goldschmidt Inforwist Esseim. Vol. 52: 22-28 (1982) translation |
| * | AT | Takada, Derwent Abstracts 87-024776/04 (JP61280435), (4/4/85)                  |

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Group 1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|   |    |  |
|---|----|--|
| * | AA | Derwent Abstract 90-255218/34, (DE4003844), 1989   |
| * | AB | Derwent Abstract 86-335072, Mizushima, (JP61249918), 1986  |
| * | AC | Derwent Abstract 87-024776, (JP61280435), 1986   |
| * | AF | Derwent Abstract 92-216793/26, Orban et al, (WO92/09299) 1990  |
| * | AG | Derwent Abstract 92-23516, Huettnerrauch, "Prepn. of carrier-dependent pharmaceuticals - by dissolving active ingredient in lower polyfunctional alcohol, melting soln. with carrier materials and a long chain organic acid and filling into gelatin capsules." |
| * | AH | Derwent Abstract 84-069426/12, Cavanak, (CH641356), 1984   |
|   | AI | The Merck Index, 9th Ed., Merck & Co., Inc., Rahway, NJ, p. 1017 (1976)  |
| * | AJ | Derwent Abstract 94-341475, Fleck et al., (DE 4412201) 1994  |
| * | AK | Derwent Abstract 96-231783, Olbrich et al., (DE 19539860) 1996   |
| * | AL | Derwent Abstract 84-282904 [46], Andrews et al, (DE 3315805)   |
| * | AM | Derwent Abstract 49-44190, Reichstein, (CH240789) 1946   |

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FOREIGN PATENT DOCUMENTS

|   |    | DOCUMENT NUMBER | DATE     | OFFICE                     | CLASS | SUBCLASS | TRANSLATION              |                          |
|---|----|-----------------|----------|----------------------------|-------|----------|--------------------------|--------------------------|
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|   | AB | 1 516 348       | 7/5/78   | Great Britain              |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AC | 97/34622        | 9/25/97  | PCT                        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AD | 589 843         | 3/30/94  | Europe                     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AE | 44 12 201       | 11/10/94 | Germany (see English Abst) |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AF | 195 39 860      | 5/9/96   | Germany (see English Abst) |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AG | 170 623         | 2/1986   | Europe                     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AH | 2120935         | 12/1983  | United Kingdom             |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AI | WO 96/36316     | 11/21/96 | PCT                        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AJ | 2098865         | 12/1982  | United Kingdom             |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
| * | AK | 87 024776       | 4/4/85   | Japan                      |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AL | 4,003,844       | 8/16/90  | Germany (see English Abst) |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
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|   | AO |                 |          |                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
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|   | AQ |                 |          |                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AR |                 |          |                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
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|   | AT |                 |          |                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|   | AU |                 |          |                            |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

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4-100-8388C  
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## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME           | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|----------------|-------|----------|-------------|
|                     | AA | 6,486,124 B2    | 11/26/02 | Olbrich et al. |       |          |             |
|                     | AB |                 |          |                |       |          |             |
|                     | AC |                 |          |                |       |          |             |
|                     | AD |                 |          |                |       |          |             |
|                     | AE |                 |          |                |       |          |             |
|                     | AF |                 |          |                |       |          |             |
|                     | AG |                 |          |                |       |          |             |
|                     | AH |                 |          |                |       |          |             |
|                     | AI |                 |          |                |       |          |             |
|                     | AJ |                 |          |                |       |          |             |
|                     | AK |                 |          |                |       |          |             |
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## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRANSLATION              |                          |
|--|----|-----------------|------|--------|-------|----------|--------------------------|--------------------------|
|  |    |                 |      |        |       |          | YES                      | NO                       |
|  | AM |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AN |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AO |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AP |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AQ |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|  |    |  |
|--|----|--|
|  | AR |  |
|  | AS |  |
|  | AT |  |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.